EXHIBIT E

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327
CONSTANCE DAINO, ET AL. V ETHICON, INC. Case No. 2:12-CV-01145	Joseph R. Goodwin U.S. District Judge

THIS DOCUMENT RELATES TO ALL

CASES

DEPOSITION OF

CYNTHIA BERGMANN, M.D.

FRESNO, CALIFORNIA

MARCH 15, 2016

REPORTED BY: Karla M. Rocha, C.S.R. No. 8982

I N D E X

EXHIBITS

DEFENDANTS' DESCRIPTION PAGE

Exhibit (None offered)

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) Joseph R. Goodwin
THIS DOCUMENT RELATES TO ALL CASES) U.S. District Judge

The deposition of CYNTHIA BERGMANN, M.D., was taken on behalf of the Plaintiffs at McCormick, Barstow, Sheppard, Wayte & Carruth, 7647 North Fresno Street, Fresno, California, commencing at 9:12 a.m., Tuesday, March 15, 2016, before Karla M. Rocha, CSR No. 8982.

A P P E A R A N C E S

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-oOo-
CYNTHIA BERGMANN, M.D.,
called as a witness herein, having
been heretofore duly sworn,
testified as follows:
-oOo-
EXAMINATION

BY MS. COPE:

Q Good morning, Dr. Bergmann. Thank you for making time for me today. My name is Breanne Cope. I am here on behalf of all the MDL plaintiffs to ask you questions about your general report about the TVT device in this case that you submitted.

Have you been deposed before?

A Yes.

Q Can you tell me how many times?

A Probably around a dozen.

Q And can you tell me were you deposed as a fact witness or an expert?

A Fact, expert, plaintiff and defendant.

Q And when was the most recent deposition?

A Probably, I'm guessing, five or seven years ago. It's been awhile.

Q Okay, was that as an expert witness?

A I'm trying to think. No, that was as a

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defendant. It wasn't that long ago. That was, like, four years ago.

Q Okay, and for the cases where you have served as an expert witness, can you tell me generally the nature of those cases?

A They have been as either a defendant, expert in a medical malpractice case, and as a plaintiff's expert in a motor vehicle accident.

Q And did either of those cases involve transvaginal mesh?

A No.

Q And when you were deposed as a fact witness, was any of that related to your medical practice or your treatment of patients?

A Yes.

Q And can you tell me generally the nature of those cases or if they involved transvaginal mesh?

A They did not involve transvaginal mesh and it was about a patient who had a pituitary injury following a motor vehicle accident.

Q Okay, and I have marked as Exhibit 1 the notice to take your deposition today.

(Whereupon Plaintiffs' Exhibit 1 was marked for identification.)

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BY MS. COPE:

Q And have you seen this document before?

A Yes.

Q Can you tell me when?

A It was sometime this weekend.

Q And if you can look to -- it says at the very top of the page, Page 5 of 8, it says, "Schedule A." And you've brought a lot of material with you today in response to this deposition notice, correct?

A Yes.

Q And the CV that you brought with you, is this different than the CV that was produced with your report originally?

A It's different. It's been updated.

Q Okay, and you also brought a number of documents that relate to your general opinions, correct?

A Yes.

Q And we can mark some of these at the break. You also brought your billing invoices; is that correct?

A Correct.

Q And can you tell me which of these billing invoices are for your general opinions for preparation of the general report as opposed to case specific?

A Probably not, because they all got lumped together.

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Q Okay, and I see the first invoice is dated May 29th, 2014, is that close to the time that you were originally contacted to serve as an expert in this case?

A I was contacted in 2014. I don't have the exact date.

Q And when you were contacted, what exactly were you asked to do as an expert?

A I was asked if I would be willing to be an expert for the defendants, you know, they asked me what I knew about meshes, did I use them, et cetera.

And that particular invoice includes a meeting with Bert Snell to go over basically -- basically, he needed to know what I knew about meshes and how I used them.

Q And did you review any materials before agreeing to be an expert for the defendants in this case?

A No, I don't believe that I did.

Q And I marked as Plaintiffs' Exhibit 2 a copy of the CV that you brought with you this morning.

A All right.

Q And I'd like to talk to you a little bit about that and your experience.

(Whereupon Plaintiffs' Exhibit 2 was marked for identification.)

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BY MS. COPE:
Q You graduated from the Medical College of Wisconsin, correct?
A Correct.
Q And do you consider that to be a good institution?
A Yes.
Q And at the bottom of the first page I see you have an internship residency, is that different from just a normal residency?
A University of Minnesota has a straight residency program, so there is no internship with it.
Q So is your being at the University of Minnesota '79 to '80 considered part of your medical school education?
A No.
Q Did you have to apply for this internship residency?
A For the residency, yes.
Q And how long is that program?
A The residency program is four years.
Q But you were only at the University of Minnesota for a year, correct?
A Correct.
Q Can you tell me why that is?

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A Because my husband got a job teaching at Tulane University in speech and rhetoric, so I transferred my residency to Tulane University at Charity Hospital.
Q And how long were you at Tulane?
A I was there for one year.
Q And why were you only there for one year?
A Because I got pregnant and did public health service payback during my pregnancy.
Q And can you explain what that is?
A Oh, I was a public health service scholarship recipient, so when I wasn't -- by the terms of my scholarship, if I wasn't in residency I needed to be paying back my public health service scholarship, which I did by working at the Public Health Department for Fresno County.
Q And can you tell me why you chose to do public health work instead of practicing on patients?
A The Charity residency was an extremely difficult -- physically difficult residency. And I already had one child at that time, I knew what it was like to be a medical student and be pregnant.
I did not think it would be fair to me, to my child or to my fellow residents to attempt a pregnancy during that type of residency. We would be on call for eight days in a row. Thirty-six hours of call was

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typical.
Q Then you eventually completed a residency at the Kaiser Foundation Hospital in Oakland; is that correct?
A Correct.
Q And can you tell me why you moved to California?
A Yes, my husband got a job at the old Valley Medical Center and I was able to move out here to do my public health service payback.
Q So the Kaiser residency, was that also just public health work, it didn't include practicing on patients?
A No, that's a full residency.
Q And it says you've been in private practice since 1985; is that correct?
A Correct.
Q And has that been with the Canterbury Women's Healthcare Group?
A Yes.
Q And that was started by your ex-husband, correct?
A And myself, yes.
Q And any particular story about why you named it Canterbury?

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A We were in the Canterbury medical complex.
Q And of the activities listed in your professional activities, can you let me know which, if any, of these involved practicing medicine versus continuing your public health role?
A I mean, well, all of them are ancillary activities. Can you be more specific as to which ones you're talking about?
Q Just there's a lot of medical -- there's hospitals listed, for instance, and I'm just trying to establish whether you treated patients in this capacity or if you were just advising them on public health.
A Well, you don't really advise on public health. As a member of the medical staff, you often serve on committees to help with the overseeing and the running of the hospital, so I think that's what you're talking about.
With the Fresno-Madera Medical Society, I was very active in helping run the organization. I was actually president twice and served their needs at both the state and national level.
Q So is it fair to say that all these professional activities involved participating on committees and not treating patients?
A No, they're not direct patient care.

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Q And it says you're a trainer for Gynecare/ Gynemesh, can you tell me specifically what you're a trainer for?
A I had been designated as a trainer specifically for TVT. Unfortunately, that came -- I was designated right before the FDA announcements came out, so I have not actually been able to train anybody.
Q Is the TVT made of Gynemesh?
A Yeah, it's the same material.
Q And you said you became a trainer around the FDA public health announcement, was that 2008 or 2011?
A 2008.
Q And what prompted you to become a trainer or a preceptor for Ethicon?
A I was asked by Ethicon to do so.
Q Do you remember who at Ethicon asked you?
A It was their local representative and I don't remember her name.
Q Did she tell you why they wanted you to be a preceptor or a trainer?
A Because they liked the way that I did the procedure. I'd had several of the reps in training in my surgeries when I was doing them.
Q And why would you have representatives in

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training watch your procedures?
A So that they could see live procedure, see how the product actually worked in the operating room.
Q And in your lectures, are these speeches or talks that you give repeatedly or are they classes that you have taught?
A Which lectures?
Q All of these. It's unclear whether these are just general talks that you have given at a conference or they're classes you've taught.
A Usually the lectures are a single lecture. They'll either be to a professional group or to a patient group. Usually it's hospital-sponsored. They'll have women's conferences and I'll give lectures about things at a women's conference, for example.
Q And do you get support from industry to attend any of the patient conferences?
A No.
Q Do you have a copy of your female incontinence lecture with you today?
A No.
Q I'd like to request a copy of that lecture.
A If I have one.
Q So when's the last time you think you gave the female incontinence lecture?

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A That would have been probably 2008.
Q And why is that the last time that you gave that lecture?
A Because the two weeks before I gave it the FDA warnings came out.
Q And what does that have to do with your lecture schedule?
A Well, as part of it we were talking about mesh as part of the conference. We were also talking about pelvic organ prolapse.
So because of the mesh controversy and it being so new, we didn't give it again. And, again, this was a one-time conference.
Q And when you say "mesh controversy," what are you referring to?
A The FDA announcement about mesh.
Q What was controversial about it?
A Well, for me, they had numerators with no denominators, so they were looking at, I thought, rather small numbers of complications given the best numbers of things that had been done.
Q And who would have access to the numbers that would be the denominators for transvaginal mesh?
A Well, the FDA should be able to have them or request them.

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Q Request them from who?
A They would be able to request them from hospitals, they would be able to request them from the manufacturers, because the manufacturers would know how many kits have been sold.
Q And are you aware if Ethicon ever provided that information to the FDA?
A No, I'm not aware of if it was provided or if it was asked for.
Q But you still believe in mesh to treat stress urinary incontinence, correct?
A Correct.
Q And you chose to stop giving the lecture because of the FDA warning instead of continuing to educate patients about the treatment method that you believe in, correct?
MR. KOOPMANN: Object to the form.
THE WITNESS: Okay, that was a lecture that was given specifically for a conference. I generally do not repeat the lectures.
BY MS. COPE:
Q So you gave it once in 2008, is that what you're saying?
A Correct.
Q To a patient group or --

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A To a patient group.
Q And what hospital sponsored it, if you can recall?
A Saint Agnes.
Q On the second page under "Certification" you list "Suburethral sling." Can you tell me what you mean by certification for suburethral sling?
A Oh, just that I had training in it and received a certificate for being able to do the sling surgeries.
Q And who is the training with?
A I did training with Ethicon. I believe that was the only -- oh, and also did training with Bard.
Q With Bard?
A Bard, yeah.
Q And the pelvic reconstruction, can you tell me is that also a training that you received a certificate for?
A Yes.
Q From which companies?
A That one was Cooke. I'm trying to remember who else. Again, this is going back to 2003. I did Cooke, we did an Ethicon course and also went to a Bard course.
Q And do you still use mesh when you're doing pelvic organ prolapse to repair transvaginally?
A Yes.

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Q And what mesh do you use for a POP repair?
A Usually I use a combination of the AMS Elevate and some type of biologic graft.
Q What biologic graft do you use?
A Currently I'm using ACell.
Q And when you say a combination of those two, do you mean you're using those same meshes in a single procedure or you use the Elevate with some patients and the ACell with others?
A I use them together.
Q And can you describe to me how you do that?
A What I'll do is do my usual dissection, put in the -- I'll take the mesh and I'll actually baste the acellular matrix to the surface of the mesh that faces the vagina.
Q And can you tell me why you don't use an Ethicon product when you do your POP repair?
A I like the AMS system the best. It gives me really good vaginal support, as well as giving the posterior compartment support. It's also very, very simple to use.
Q Is simplicity of use an important feature in a medical device, do you believe?
A Well, it makes things more efficient in the operating room, cuts down on your operating time.

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Q You can put your CV aside. Did you also found some sort of endometriosis institute?
A It's when we started our practice, we were doing a lot of endometriosis surgery and there was -- so we set up something called the Endometriosis Institute. We've never actually used that, but I believe we still own the name. So if you know anybody who would like to buy it, it's available.
Q And your practice now, in terms of physicians, consists of you and your ex-husband; is that correct?
A Correct.
Q Do you know if Ethicon has ever asked your ex-husband to be a consultant in this litigation?
A Not that I'm aware of.
Q And how many days a week do you currently see patients in your practice?
A Well, I see patients five days a week. Four days we're in the office and then we have a day doing surgery.
Q And you treat women for stress urinary incontinence in your practice, correct?
A Correct.
Q What percentage of the women that you treat for stress urinary incontinence are housebound because of their SUI?

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A I don't know of any that are currently housebound, but I would imagine they would quit coming to see me if they were housebound.
Q You think they would stop seeking medical treatment if they were housebound --
A If they're truly housebound, they would not get out of their houses. I do have women where it has a severe negative impact on their lives.
MR. KOOPMANN: Just make sure you let her finish her question.
THE WITNESS: Sorry.
BY MS. COPE:
Q What percentage of the women that you treat for SUI report chafing of their vulva from wearing panty liners or pads?
A As far as report, it's generally in their examination I'll see that they have a dermatitis from wearing pads and I'll ask them about it. I would estimate that somewhere between -- and, again, it's an estimate, between 40 and 50 percent have some type of dermatitis from wearing pads.
Q But they don't report symptoms to you, it's something you observe during the exam, correct?
A It's observed and asked about and patients admit to the symptoms.

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Q And what are the symptoms?
A Burning and itching, irritation of the vulva.
Q And what percentage of the patients you treat for SUI report vaginal infections from wearing panty liners or pads?
A Well, I don't believe that they -- I don't know that -- well, usually they don't come in saying, "I have stress incontinence and a vaginal infection." They'll come in saying they have a vaginal infection and as part of it I will ask them whether or not they're wearing pads. And if they're wearing pads consistently then we talk about other ways of managing their problems.
And as far as percentage, that would be limited to my patients 50 and older. So if we want to limit it to that, I would say a third of them wear pads.
Q I just want to know of the ones that do wear pads, how many of them have vaginal infections that you believe are caused by using panty liners or pads?
A I don't believe that wearing panty liners or pads are necessarily the cause. It would be the organism, not the pads.
Q And by "organism" what do you mean?
A Say a yeast infection or a bacterial infection.
Q Okay. Can you tell me the racial makeup of your patient population?

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A We're about 50 percent Hispanic, 35 percent white and the rest are divided among Oriental, African-Americans and Native Americans.
Q And what percentage of the patients that you treat for SUI are overweight?
A It's Fresno, everybody is overweight. I would say at least two-thirds of my patients are overweight, so I -- and it's not something I split out particularly when I'm addressing stress incontinence.
Q How many surgeries have you performed in your career to treat stress urinary incontinence?
A I don't have a number.
Q Over 1,000?
A I would -- I'm sure it's over 500. It could be 1,000. I don't keep records that way.
Q What way?
A I don't track the number of cases that I do or particular cases.
Q You started using the TVT in 2001; is that correct?
A No, 2003.
Q I'm going to show you what's been marked as Exhibit 3, which is the report that was produced in this litigation.
(Whereupon Plaintiffs' Exhibit 3 was marked for identification.)

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BY MS. COPE:
Q And on Page 2 under Paragraph B you state that in 2001 your partner and you were trained in the use of the Ethicon TVT device.
A Yes.
Q So you were trained in 2001, but didn't start using it until 2003?
A Correct.
Q And why didn't you start using it until 2003?
A Well, because it was a new device that had to be approved by the hospital. It took us a year and a half to get the hospital to approve our using the device.
Q And can you explain to me the approval process for the device with the hospital?
A You know, I've not been on those committees, so I'm not sure what goes on, other than they have to decide whether or not it's cost effective for them, which is the biggest thing, whether or not they want to stock it if it's a procedure they want to do in the hospital.
Q I believe you testified that it took you a year and a half to get it approved, but you didn't mean you personally; is that correct?

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A I'm sorry?
Q You --
A Oh, no, no, it wasn't -- again, once the device is approved, anybody who shows sufficient certification to do it can do it.
What I can say in general is that every hospital has their own requirements for how the approval process goes for physicians and that's up to the medical staff.
Q Well, before you were talking about getting the actual device approved to be used in the hospital --
A Correct.
Q -- and not physicians who are able to use the device. So just in terms of the hospital being willing to carry the Ethicon TVT device, do you know anything about that process?
A Again, all I was told was they had to make sure it was cost effective. There was -- I am aware that there was one person on that committee who didn't think that it was appropriate for gynecologists to do this type of surgery, even though at the time my partner was training in pubovaginal slings.
Q You said your partner was training in pubovaginal slings, were you also?
A No, he was training.

Q And did you ever ask the person on the committee who disagreed with the use of the TVT device why they disagreed or what their reasoning was?
A No.
Q Do you know that person's name?
A Yes.
Q What is it?
A Bernie Freeberg.
Q And then you state in the next sentence of your report that suburethral polypropylene mesh slings became your surgical treatment of choice for SUI, correct?
A Correct.
Q Can you explain to me why, after your training, they became your surgical treatment of choice?
A They're simple to use. They're very effective. It's a short surgery. The patients have a quick recovery, back to normal function quickly. It's long lasting. I found it far superior to the Burch -- colposuspensions that we were doing previously.
Q What do you mean --
A I'm sorry. I'm sorry, go ahead.
Q You said they were long lasting, what did you mean by long lasting?
A Well, I've been doing them since 2003, I've had one failure in that time.

Q But when they became your surgical treatment of choice in 2001, you hadn't been using them for that long?
A I hadn't been.
Q How did you know they were long lasting when they became your surgical method of choice?
A By the data that had been presented.
Q And what data was presented to you in 2001?
A Dr. Ulmsten's studies had been presented.
Q And how long had the follow-up been at that point in 2001 for the TVT device?
A I believe that he had data that was between five and seven years at that point.
Q And who provided that data to you?
A Well, it was in our journals. We got copies of reprints when I went to the courses.
Q When you say "courses" you mean Ethicon training courses, correct?
A Correct.
Q How did you surgically treat stress urinary incontinence before you started using the TVT?
A With Burch.
Q Any other procedures?
A No. At that point, Burch was the most effective method that I had available to me.

Q And did you ever have a patient that had a complication from anesthesia with the Burch procedure?
A From anesthesia?
Q Yes.
A Not that I'm aware of.
Q Ever have a patient that you performed a Burch procedure on present with chronic pain related to the Burch procedure?
A No.
Q And currently you state in your report that you use the -- strike that.
You said you were trained in a variety of products, including the TVT and the TVT SECUR, correct?
A Correct.
Q Do you use the TVT SECUR any longer?
A No.
Q Can you tell me why that is?
A I didn't like its placement method as well. I use the AMS MiniArc instead.
Q And you still use the MiniArc today, correct?
A For today, yes.
Q And the AMS ASTORA RetroArc, do you use that device as well?
A I use the RetroArc.
Q And the Bard and Boston Scientific slings that

you were trained on, did you ever use those for more than one or two procedures?
A Yes. I think I did four, maybe five with the Boston and probably did a dozen with the Bard.
Q And why only 5 and 12 of those products?
A I did not like the mesh for the Boston. We had problems with it. It didn't erode, it didn't expose, the edges actually were frayed and poked through the mucosa and they couldn't explain why that had happened, and short of an explanation, I was not willing to use the product again.
And the Bard had a great delivery system, very simple to use, but the mesh shrank more than the other meshes so that we had -- almost a third of the patients had urinary retention with the Bard, so we quit using it.
Q And how quickly did you see that urinary retention in patients you treated with the Bard device after implant?
A That would usually arise somewhere between four and six weeks afterward, or even later, which was one of the problems. When it's early on it was easier to correct, but if it occurs later then you've got to go in and split the mesh.
Q And by "later" can you just tell me what you mean, time-wise?

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A Anytime after six weeks.
Q And you said that the Advantage Mesh frayed and poked through patients' mucosa, did you believe that that was a problem with the product?
A Again, I had one patient where that happened. For me it was a problem. If the company had been able to tell me why it happened and there was a way to avoid it, I might have continued using it.
Q Can you tell me what you mean by "the product frayed"?
A Well, I mean, you know what fraying is?
Q That's my definition of fraying, I want to know what yours is.
A Okay, well, if you have a piece of material, the edge should be solid. If the threads come undone, I think it's the wolf, which is the cross threads, will be out and that's a fray.
And that appears to have happened with the mesh, so we had those little ends sticking out. There were probably a half-dozen of them or more.
Q And why did you consider that a problem in treating your patient?
A Well, it was not very comfortable for a husband when they tried to have sex.
Q And I imagine it wasn't very comfortable for

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your patient either?
A Actually, she didn't feel it.
Q And are you aware that American Medical Systems is going to stop producing their mesh products?
A I know that they're going to stop selling them in this country. I don't know if they're stopping them in Europe or not.
Q So do you have any plans on how you're going to treat your patients if the RetroArc and MiniArc are no longer available?
A Well, I know the product is good for the next year. So, again, I use TVT for most of my slings. For the patients where I use the MiniArc, now I'll be using a TVT instead.
Q And can you tell me how you make the decision in a patient whether you're going to use the TVT, the RetroArc or the MiniArc?
A It's basically, first of all, what the hospital supplies and has available, because they have contracts with various groups. So at certain hospitals you can get one type of mesh, at another hospital you can get another.
But, basically, for me, patient selection is if I have a patient who weighs more than 200 pounds or if they're very physically active or have a child where

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they're going to be doing some type of lifting, then I tend to put in the longer mesh rather than the short mesh.
Q And by longer mesh you mean the TVT?
A TVT or RetroArc, yes.
Q So other than body weight and their activity level, is there any other patient selection criteria you use when deciding which sling you will implant?
A Other than having the fact that they actually have stress incontinence. The patient has to have a desire to have the sling done. We go through a workup, we look at other modalities of treatment, physical therapy, do Kegel exercises, weight loss, et cetera.
Q So if you have a patient that's under 200 pounds, are those three devices interchangeable to you for treatment?
A For under 300 pounds?
Q Under 200.
A Yeah, I think they would be pretty much interchangeable, again, depending upon their activity level. For example, if we're talking about 120-pound nurse, she's going to be lifting 200-pound patients, that kind of patient I will use the retropubic slings instead of a MiniArc.
Q And would you agree with me that there's a

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difference between post-operative pain and chronic pain?
A Not knowing what you -- do you want me to define them or. . .
Q Sure.
A Okay, post-operative pain would be pain that we would expect in the immediate post-operative period, usually resolved within 6 weeks to 12 weeks. And chronic pain is any pain that is long lasting and not necessarily related to an operation.
Q Can chronic pain from the TVT device develop many months after it's been implanted?
A I have never seen that.
Q I understand you have never seen it, but is it possible?
A To the extent that anything is possible, I assume that it would be.
Q And do you believe it's important to have scientific data before implanting a permanent medical device into a woman?
MR. KOOPMANN: Object to the form.
THE WITNESS: Who is the "you"? You mean as a physician?
BY MS. COPE:
Q Yeah.
A Okay, as a physician I think that it behooves

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us to research any device, medication or procedure that we do on a patient, and make sure that it's appropriate for us to use and make sure that we're using it on appropriate patients.

Q And what do you mean by "research"?

A That we review the literature, look at the risks and benefits of what we're doing or giving to the patients. And then, of course, knowing the individual patient, their medical history and their particular anatomy and physiology to see if whatever we're doing for them is the best thing for that patient.

Q So it's important for you to have scientific data before you put a medical device into a woman's body, correct?

A That would fall within those categories, yes.

Q And you wouldn't implant any device into a woman that's going to be there for her entire life without having some data to rely on that establishes the safety of the device, correct?

A Of the implant, yes.

Q Or the efficacy of the device, correct?

A Correct.

Q And that would apply to any type of implant, not just transvaginal mesh, correct?

A As I said, anything we do for patients.

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Q And other than the Ulmsten data that you mentioned previously, what other data did you look at to make sure the TVT was safe and effective before you began using it?

A Again, I know that we looked at other data. I don't have the names of that data at this point.

Q Did you review any of that to prepare your report in this case?

A No, no, at this point that's old data.

Q Can you tell me what you recall about your training session with Ethicon regarding the TVT device?

A We had an in-classroom session first, going over the need for the device, going over stress incontinence, the impact of stress incontinence.

We then reviewed the data regarding the TVT, its efficacy data, its safety data, and then they showed us -- I can't remember if we had a video and slides or just slides showing how the device was implanted.

Then we did passes with models first so we could get an idea of how it would interact in the pelvis and then we did a cadaver lab.

Q And, again, other than the Ulmsten data, you don't remember the source of the information that was supplied to you, correct?

A No -- correct.

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Q And do you have any other materials that you received from that training session today?

A No.

Q And can you briefly describe for the jury how you were trained to perform the TVT procedure?

A I'm sorry, to the jury?

Q So this deposition will be for a jury.

A Oh, okay. I was just like there's somebody here I don't know about.

Q They're all the same.

A I'm sorry, go ahead and repeat the question.

Q Can you explain to me how you were trained to perform the TVT procedure?

A Well, just what I said, we had a didactic session --

Q I'm sorry to interrupt you, I mean the actual procedure itself, if you could walk me through.

A Oh, you want to know how I perform it?

Q How you were trained to perform it.

A How I was trained to perform it, okay. What I was trained to do is have the patient in the dorsal lithotomy position with the legs at a 60-degree angle so you don't have the pelvis over-rotated, to make a mark superpubically one and a half to two centimeters off of midline.

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You can do it with a marking pen. My habit is to just use the scalpel that I'm going to use to make the incision anyway, so I've got a mark. You have to be careful to make sure you're actually in the midline, especially with obese patients, because their midline can appear to be in one place and it's actually in another.

Then put in an 18 French catheter with a large bulb, blow that up. Using my left hand in the vagina, I then take a spinal needle, I usually use an 18 or 20-gauge spinal needle, and inject 20 cc's of .0625 percent Marcaine solution on either side of the urethra. I have personally modified that now to be 60 cc's on each side.

Then I'll put a weighted speculum in the vagina. I'll make a midline incision in the mid-urethra, grab the edges of that with the Allis clamps undermined at about a 45-degree angle, making sure the undermining is no more than a centimeter wide.

At that point, we will put a urethral guide through the catheter, deflect the urethra. Usually I do my right pass first so we deflect the urethra to the left side. I'll take the needle, I'll run it at about a 45-degree up to the endopelvic fascia and then I go straight vertically from that, hugging the back of the

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pubic synthesis, bringing the needlepoint out at the incision that I have made on the ipsilateral side.

At that point I will take out the catheter, do a cystoscopy, ensure that I haven't perforated the bladder. I then do the same procedure on the opposite side.

At this point I will usually instill 500 cc's of Methylene Blue sustained normal saline into the bladder. That does two things. It stretches the bladder a little bit, because many of these patients have a rather small bladder, because they keep their bladders empty so they don't have public embarrassment from losing urine.

It also will let me know if I have any occult holes in the bladder, because if I do, then we'll see blue dye coming out of the pubic or the vaginal incisions.

Once I have ensured bladder integrity, I will then advance the mesh. I will take out the weighted speculum. At this point, of course, the Foley catheter is out, the cystoscope is out. I will use a nine Hegar to space the mesh from the urethra. I'll make sure that that's not under any tension.

We will then gently remove the sheaths from the mesh. I will, again, check to make sure there's no

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tension between the urethra and the vagina.

At that point I will re-insert the weighted speculum, close the vaginal incision with interrupted sutures in number 3-0 chromic. The excess mesh is trimmed superpubically. I will do that actually before I remove the Hegar dilator for spacing, just so in case there's any tension on the mesh we don't transmit that.

So once that's trimmed, the vaginal incision is closed, then I close the superpubic incisions, and I'll use 3-0 VICRYL for that, steriostrip it.

I'll put in a 12-inch Foley catheter, take the patient out of the dorsal lithotomy position, and they go to recovery.

Q And do you leave a catheter in your patients ever after performing the TVT?

A I always leave it in overnight.

Q And why is that?

A Because in Fresno if you need to go to the emergency room to get a catheter put back in it will be six to eight hours before you're seen and have that done.

Most patients don't mind having the catheter in overnight verses trying to wade through an emergency room, particularly because I do most of my cases on Fridays and so they've got the Friday night knife and

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gun club to contend with if they would have to go to the emergency room.

Q And following your training on the TVT device, how many procedures did you observe before performing your own?

A I think it was either four or five procedures that we saw.

Q And those were on live patients?

A Yes.

Q And how many procedures did you assist on before you performed your first TVT procedure?

A I didn't assist on any before I performed my first TVT procedure.

Q And the procedures that you observed, were those done by the Ethicon preceptor?

A Yes.

Q And who was your preceptor?

A I don't recall his name. It was out of Santa Maria Hospital.

Q Did you tell the woman that you first implanted a TVT into that it was your first time doing that procedure?

A Yes.

Q And when you were contacted to become a proctor in 2008, I believe, can you tell me the process for

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becoming a proctor?

A I was told that they had appointed me a proctor and that they would be sending physicians to me to observe me doing the procedure and that I would proctor them and, as I said, after that nothing happened.

Q Did they tell you how much you would be paid to do that?

A No.

Q And when Ethicon representatives come and observe you, how much are you paid for that?

A Nothing.

Q Do you tell your patients that there will be a third party in the room while you're performing the procedure?

A If I have observers that they actually have to get consent from the patient to be in the OR.

Q And when a woman comes to you for treatment or for stress urinary incontinence, can you walk me through the process you use to reach a diagnosis?

A Well, first thing I do is take a complete history and physical. I'll ask them when they're losing urine, how much they're losing, how often they're losing, what sets it off. I ask about can they make it to the bathroom, so I'll ask about other types of incontinence at the same time.

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In the examination I will look for anterior rotation of the urethra with Valsalva to see if they have loss of urethral vesicle angle with pressure.

I will frequently suggest -- obviously, if they're obese, I'll suggest that they try to lose weight. A lot of them tell me they have difficulty because whenever they try to exercise they'll continue to lose urine. I have them do Kegel exercises.

Q I don't mean treatments, I just mean your diagnosis.

A Oh, okay, sorry. So that's -- so we'll start out with history. If they get to the point where they are considering surgery because other methods have failed, which is why I was going to the other methods, then we do cystometrograms and urodynamics to determine that it's actually stress incontinence and not some other type of incontinence.

Q Do you do a pelvic exam to diagnose SUI?

A Yes, that's when I was talking about the anterior rotation of the urethra, that's part of the pelvic exam.

Q Do you do a breast exam to diagnose SUI?

A I do that as part of my -- if the patient comes in de novo with stress incontinence they do get a breast exam.

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Q And what about an oral exam?

A Yes.

Q And why is that?

A Because if I don't look, you never know what you're going to find. For example, doing an oral exam I might find somebody who's actually bulimic, you can see the loss of enamel on their teeth.

Q What does that have to do with your treatment of their stress urinary incontinence?

A Well, when you throw up you tend to lose urine. And they may also have a psychological component that we need to address.

Q So you do an oral exam on patients to determine whether they have an eating disorder?

A It's among other things.

Q What are the other things?

A What their general hygiene is, whether or not they have missing teeth. That's really important if you're thinking about putting someone under anesthesia, if they have loose or missing teeth those can get knocked out. They can have aspirations.

Q Do you allow a woman to bring her husband or someone else into the exam room with her if she wants?

A Whoever she would like in the exam room.

Q Have you ever told a patient she cannot bring someone with her into the exam room?

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A Not to my knowledge.

Q And you stated that you perform urodynamics testing, correct?

A Correct.

Q And do you give informed consent for that?

A No, it's part of our general consent.

Q In diagnosing your patients with SUI, do you ever perform cystoscopies?

A No, I don't perform cystoscopies in the office.

Q Do you perform them in the hospital?

A Yes.

Q Outside of doing a pelvic floor surgery?

A No.

Q And do you give informed consent for cystoscopies?

A Yes.

Q And can you tell me what informed consent is?

A Informed consent is a process of reviewing with the patients the risks and benefits of the particular procedure you're planning to do.

Q And a patient has the right to know of all the inherent risks, correct?

MR. KOOPMANN: Object to the form.

THE WITNESS: Of all of the relevant inherent risks.

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BY MS. COPE:

Q And what do you mean by "relevant inherent risks"?

A Again, anything can happen to a patient or in the operating room, so we go over the generally accepted risks of a procedure. If something is one in a hundred thousand, I probably would not mention that as a risk, but anything that's more common we go over.

Q And what do you mean by more common?

A Risk of death, for example, is usually around 1 in 10,000 or less. We go over the risk of death.

Q So you'll warn about anything that is greater than or equal to a risk of 1 out of 10,000; is that correct?

A Again, in general.

Q And is that what you mean when you say generally accepted risks, the more common ones?

A Correct.

Q And the purpose of informed consent is to give patients that information about risks, correct?

A To give them the opportunity to be involved in their care and their medical decision-making.

Q And you would never make a decision on behalf of a patient without her consent, correct?

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A As long as the patient was able to give consent.
Q And patients have the right to refuse to consent to medical treatment at any time, correct?
A Correct.
Q And there's lots of different reasons why a woman may decline to have a cystoscopy or a procedure, correct?
A Correct.
Q And currently what treatment options do you give to women who want a surgical intervention for their SUI?
A Currently it will be one of the slings.
Q You don't perform any non-mesh procedures to treat SUI?
A No.
Q Do you tell the patients of the different sling options?
A Yes, I do.
Q And can you tell me what you tell your patients about the different sling options?
A Again, it's the same process that I went through with you before. I will ask them about their activity level, specifically if they do repetitive lifting. My horseback riders, for example, are lifting,

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you know, 20 to 40-pound saddles onto their horses, they tug bales of hay.
Nurses. If they're teachers, they teach young children, they frequently have to pick them up and move them around, so we determine that.
I tell them my experience with the shorter slings versus longer slings, when I find them more useful or less useful, so I'll present that information to them.
Q Do you tell your patients who the manufacturers of the slings are?
A No.
Q And why do you give your patients the different options between the slings?
A For the reasons I stated before. Did you want me to go over them again?
Q I just meant why you would present a patient with different options for treatment?
A Because I think patients need to be involved in their medical care. That's part of the medical decision-making process.
Q And you give your patients informed consent before planning any of those mesh slings, correct?
A Correct.
Q And including the TVT?

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A Correct.
Q Do you have a standard informed consent that you use with your patients that you implant a TVT in?
A Yes.
Q And did you bring a copy of that with you today?
A No.
Q So I would like to request a copy of her TVT informed consent.
Can you explain to me the risks of the TVT procedure?
A Okay, general risks is -- what I tell the patients is given where we are we can injure the bowel, the bladder, the urethra, the major blood vessels. There's a risk of infection of the vagina, the bladder, IV sites, lungs or bronchitis or pneumonia.
We could run into a lot of bleeding, either as a result of an injury or as a normal part of the procedure. If the bleeding is bad enough, that can entail more surgery, it can entail receiving blood transfusions. Blood clots in the legs are possible.
You can have reactions to medications, nausea, vomiting, wheezing, dizziness, rashes, death is a possibility. With using mesh, it's a permanent implanting device, there's a risk of either erosions or

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exposures of the mesh.
Q What are the potential longer term complications that you discuss with your patients regarding the TVT?
A We do discuss that there's a chance that they will fail over time.
Q And when you mentioned the infection of the vagina, bladder, can you explain to me what you mean by infection?
A Occupation of the spaces with bacteria that normally don't live there.
Q In the immediate post-operative period?
A Yes. We also go over the risk of urinary retention. We go over the risk that the sling may not work for them, they may continue to be incontinent. We talk about urge incontinence.
Q What do you talk about specifically in regards to urge incontinence?
A That they may develop an urge incontinence that can be as a result of age and time. It's more frequent in older women. That their prolapse may actually be masking their urge incontinence by kicking off the urethra. And, again, that doesn't tend to be so much with people who have just stress incontinence and not other pelvic organ prolapse.

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Q And just to clarify, the discussion about urge incontinence, is that because it's a specific risk related to TVT?
A It's a known risk that it can be, that there can be more urge incontinence afterward.
Q Any other longer term complications that you discuss with your patients?
A Not that I recall right now.
Q Have you ever had a patient who declined a mesh sling that you recommended?
A Who then went on to other surgery?
Q A patient who you had this informed consent discussion process with and afterwards decided not to proceed with the mesh implant.
A No.
Q What complications do you see with the TVT during surgery?
A Personally?
Q Yes.
A None.
Q So you stated that you warn your patients of common risks?
A Correct.
Q But, clearly, for you, these risks are not common, correct?

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A Correct.
Q So where do you get your understanding of which risks are common or not if it's not from your clinical experience?
A Literature.
Q And what complications do you see with the TVT after surgery?
A Urinary retention is -- did I have anything other than -- urinary retention and then early on had a handful of cases of exposure.
Q What's the difference between erosion and exposure?
A Exposure is failure of coverage. Erosion is something actually moving through a tissue.
Q And can you explain to me what you mean by failure of coverage?
A What we found after doing this for a while, and I can't tell you how long, some patients have -- I don't want to call it an anomaly because it really isn't. It's a variation of how the mucosa covers the urethra, and so instead of having a relatively smooth covering, they'll actually have two little wings that kind of come out and then it dips in at the mid portion, and when they have that kind of coverage of the urethra you have to put in your sutures a little differently than you do

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if it's a smooth covering.
Q And how do you put your sutures in differently for those with this physical anomaly?
A Instead of doing a simple closure I'll do a mattress suture, so that will evert the edges of that incision so it comes together.
Q And when you were answering my question earlier you said, "What we found."
A Oh, my partner and I.
Q What complications has your partner seen during the TVT surgery that you're aware of?
A That I'm aware of, he's had one bladder perforation that was not with the TVT. I know he's had some retentions. I don't know if he's had the exposure problem or not.
Q And the bladder perforation, that was with the retropubic device?
A Yes. I think it was the Boston Scientific, but I'm not positive.
Q And how do you treat urinary retention in your patients?
A Depending upon when this occurs, if it's in the first two weeks we do catheterization. If it's longer than that, say between two and four weeks, I'll actually try to mobilize the urethra and the sling in the office

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using a dilator.
If it is after that or if it occurs later on, then what I'll do is take them back to the OR, simply divide the sling in the middle and close the mucosa over it.
Q And approximately how many times have you had to go back into the OR to address urinary retention?
A Maybe half a dozen.
Q And how do you treat your patients with exposure of the TVT mesh?
A It depends upon -- if it's not much exposure we'll just uses estrogen cream and generally mucosa will grow over. If it's a larger exposure, either put in a suture in the office to reclose, and I don't believe I've had to take anybody back to the operating room to close a sling exposure.
Q And when you say it's not much, can you sort of define for me size-wise?
A It's probably like the four-millimeter range.
Q So anything greater than four millimeters, you put in a stitch in the office?
A I'll -- well, I don't -- again, trying to remember how big the largest one was. Most of them we'll try treating with estrogen cream first. And, again, I don't recall one that has been that big that I

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would go primarily to closure. We usually try the estrogen cream first.
Q When you do go to closure, what suture do you use?
A I'll use a chromic suture, usually a 2 or 3-0.
Q And what material is the chromic suture made of?
A Chromic cat gut. It's cat gut that's, I believe, chromic coated.
Q Is it a dissolvable suture?
A Yes.
Q And why do you use a dissolvable suture?
A Well, the mucosa in the vagina heals up like the inside of your mouth, so when it heals, it heals rather quickly, so you want something that's also going to go away fairly quickly, that reduces your risk of getting any type of fistula formation.
Q So you don't use polypropylene sutures in the vagina, correct?
A In the vagina to close the mucosa, no.
Q In the vagina for any purpose?
A I have never used polypropylene sutures in the vagina.
Q And approximately how many TVT procedures have you performed?

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A I have done in the 250 range.
Q And how many RetroArc procedures?
A RetroArc, because they just came out with a type I liked about a year and a half ago, so maybe 25 of the RetroArcs.
Q And how many MiniArcs?
A MiniArcs, again, my guess is probably about 150.
Q So if I add up those numbers correctly, over the course of your entire career you have performed 425 sling procedures to treat urinary incontinence?
A That sounds reasonable.
Q When you're using the TVT do you use the mechanical cut or the laser cut?
A Whichever one the hospital has in.
Q So you don't make a specific request for either one?
A No.
Q Do you specifically request the TVT or the RetroArc or the MiniArc?
A Yes.
Q Have you ever had an occasion where you show up to do a procedure and the sling that you requested is not present?
A Yes.

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Q And how did you address that?
A Usually with the materials manager and the head nurse.
Q What did you actually do for the procedure, though?
A I have been fortunate that I have not had a case where that's happened with a patient asleep on the table. So we will either cancel the surgery if they don't have the appropriate equipment in or we can generally, because we have reps in town, we can generally get another device either from the representative in town or from another hospital.
Q And did any representatives talk to you about your work as a legal expert for Ethicon?
A No.
Q And do you have any idea of how many of the 250 TVT devices you have implanted were mechanically cut?
A No.
Q So you would have no idea how many of them are laser cut either, correct?
A Correct.
Q Has Ethicon ever told you that there were different risk profiles for the mechanically cut versus the laser cut TVT device?
MR. KOOPMANN: Object to the form.

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THE WITNESS: No, they haven't.
BY MS. COPE:
Q Has anyone at Ethicon ever told you that the mechanically cut TVT can fray?
A No.
Q That the mechanically cut TVT can rope?
MR. KOOPMANN: Object to the form.
THE WITNESS: They haven't told me, but I am aware that it can.
BY MS. COPE:
Q And how are you aware that it can rope?
A I have tugged on the meshes myself.
Q And can you tell me the context in which you were tugging on the meshes yourself?
A Oh, in demos, people would bring me a piece of mesh.
Q And so what happened, you pulled on the mesh?
A Pull on it to see how much tension you can put on it.
Q And what happened to the mesh?
A If you pull hard enough, it will rope.
Q And that was with Ethicon Prolene Mesh?
A It was with almost every mesh out there.
Q Anyone at Ethicon ever tell you that the TVT device can curl?

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MR. KOOPMANN: Object to the form.
THE WITNESS: Again, that was something that I observed myself, Ethicon did not tell me.
BY MS. COPE:
Q Anyone from Ethicon ever tell you that the TVT device could release particles?
MR. KOOPMANN: Object to the form.
THE WITNESS: No.
BY MS. COPE:
Q Anyone from Ethicon ever tell you that the TVT device can degrade?
MR. KOOPMANN: Object to the form.
THE WITNESS: No.
BY MS. COPE:
Q So when you implant a TVT in a patient, you don't know whether it's laser cut or mechanical cut, correct?
A Correct.
Q And can you tell me what you did to prepare for today's deposition?
A I went over my -- you're talking about just this part of the deposition, correct, not everything else we're going to do?
Q Once you found out you were going to be deposed for your general opinions, what you did to prepare for

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this deposition.
A Okay, I went over my general report and I gathered the information that you asked for.
Q And was that before or after March 1st, 2016?
A That was after.
Q So can you approximate for me how many hours you spent since March 1st of 2016 on your work on this case?
A For just the general report or for everything?
Q Just the general. If you can't do that, everything.
A Can't do just the general report. And I would have to look for everything. I know it was eight hours yesterday and then I'd have to go back and look to see what else since March 1st.
Q And did you meet with any of Ethicon's attorneys to prepare for today?
A Yes.
Q For approximately how long?
A We met for seven hours yesterday.
Q Any prep over the phone with an attorney?
A One of the preps was over the phone.
Q And how long was that?
A I think we spent about an hour and a half.
Q And you received money from pharmaceutical and

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medical device manufacturers, correct?
A From pharmaceutical manufacturers, not from medical device manufacturers.
Q And are those the manufacturers that are listed on the pharmaceutical speakers' bureaus portion of your CV? I guess the second to the last page.
A Correct.
Q And can you tell me approximately how much money you have received from pharmaceutical companies?
A No.
Q Can you tell me what you've done for Shiongi, if I'm pronouncing that correctly?
A I speak for a product they have called Osphena.
Q Are you involved in the clinical trial of Osphena at all?
A No.
Q And how much are you paid by Shiongi?
A For in-town lectures, 750 to 1,500, depending upon the type of lecture, whether it's a lunch or a dinner. And out of town, I believe, is 2,500.
Q And when did you start working with Shiongi?
A I believe I started with Shiongi about two years ago. It was 2014. Might have been 2013.
Q And if I told you you received $25,000, approximately, from them in 2013, would that sound

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accurate to you?
A 2013 or 2014?
Q 2013.
A That doesn't sound right. It would sound right for 2014. Unless -- I don't know if they're including -- because I assume you've looked that up on the federal database, correct?
Q I have.
A Okay, that may include the training sessions that they sent us to.
Q But you're paid to attend those as well, correct?
A I'm paid to attend them, but not $25,000.
Q Well, that's approximately what the total amount that you were paid for in 2013 shows on the CMS Open Payment database, and 17,000 in 2014. Did you have any reason to dispute those amounts?
A Again, I haven't even gone and checked those. That's not what I believe I received in actual compensation for them. My understanding is the CMS database includes travel, hotels, our training sessions, et cetera, so I don't have any reason to dispute them, but that's not what I actually received from them.
Q Does anyone travel with you when you go to these speaking engagements or trainings?

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A No.
Q And approximately how many Ethicon representatives do you believe have come in to observe you over the years?
A Ethicon, maybe four or five.
Q And what was the time frame for that?
A Oh, that would have been from 2005 to 2007 or '08, I believe.
Q And what types of questions would the sales representatives ask you?
A I don't recall any specific questions at this time.
Q Do you recall anything specific that you would tell the representatives?
A I would just show them how I would do the procedure. I would ask them if they had any questions about what I was doing or how I was doing it.
Q Let's take a quick break.
(Brief recess.)
BY MS. COPE:
Q Doctor, you'll agree with me that the TVT is designed to be permanently implanted in a woman's body, correct?
A Correct.
Q And you agree with me that TVT mesh can cause

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harm to a patient years after it's implanted?
MR. KOOPMANN: Object to the form.
THE WITNESS: That's not been something I have experienced.
BY MS. COPE:
Q But you agree that it can happen, correct?
MR. KOOPMANN: Object to the form.
You can answer.
THE WITNESS: Again, it's not something that I have experienced.
BY MS. COPE:
Q Have you read about it in medical literature?
A What I have read about I have seen -- again, just for the TVT mesh there's problems that have occurred at the time of surgery that become recognized later, is that what you're talking about?
Q I'm talking about a patient that's had the TVT device implanted and years later has injuries from that device.
A Okay, you'd have to give me a specific type of example.
Q You can't think of anything that you have read in the medical literature or heard from colleagues?
A Where the device has, years later, caused problems?

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Q Yes.
A That was a properly implanted device?
Q Correct.
A Again, not that I know of.
Q Are you aware that many of the studies that you have sited in your report don't track long-term complications?
MR. KOOPMANN: Object to the form.
THE WITNESS: Again, you'd have to tell me the specific studies so we could go over them. I know I have several other studies that show long-term.
BY MS. COPE:
Q I'm just talking about the ones that have been sited to you in your report for your --
A I'm aware that there are also studies sited which have long-term results. I have also read studies that have long-term results.
Q And I'd like to show you what I have marked as Exhibit 4.
(Whereupon Plaintiffs' Exhibit 4 was marked for identification.)
BY MS. COPE:
Q This is the one from 2015, which is from Ethicon's website.
A Okay.

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Q And I will represent to you that I have only printed the English pages, not the entire document.
A Thank you. So I don't have to use my Sylvanian today.
Q I'll just give you a minute to review that. Have you seen this document before?
A Yes.
Q And when did you see this document?
A Looked at it last year. Don't recall exactly when.
Q And if you look on Page 5 the second bullet point reads: "Prolene Mesh in contaminated -- " sorry. "Prolene Mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material."
A Where is that?
Q The second bullet point in the top.
A All right.
Q Do you agree that the vagina is a clean, contaminated area?
A Well, that's the -- we can use that term or non-sterile.
Q What does the term "clean, contaminated" mean to you?
A Well, surgically it's -- we know the vagina

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carries bacteria, you can't sterilize it, just as you can't really sterilize the skin, so there may be some residual bacteria in the vagina.

Q And Page 5 continues. There's an "Adverse reaction" section and then an "Other adverse" reaction section, correct?

A Correct.

Q I'll just give you a minute to review that. Let me know when you're finished, please.

So would you agree with me that the TVT mesh device can cause all of the items listed in the adverse reactions and other adverse reaction section of this document?

A Well, they have it in here. Again, as I said before, this is something -- some of these are things that I just haven't seen. The recurrence of incontinence, certainly. Bleeding we talked about. Division surgeries.

Q Well, why would Ethicon put these adverse reactions or other adverse reactions in the warnings for their product if they weren't possible?

MR. KOOPMANN: Object to the form, foundation.

THE WITNESS: I don't know why they would do that. I would assume that it has something to do with either their studies or what they need to do for the

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FDA.

BY MS. COPE:

Q So is it your testimony that the items that are listed in these two sections, there are some things that are not caused by the TVT device?

A Again, as I said before, some of these things are things I haven't experienced.

Q I didn't ask you what you had experience, I'm asking you if you'll agree with me that these are things that can be caused by the TVT and that's why they are in the instructions for use as potential adverse reactions to the TVT device?

A Again, I don't know why they would be in there. I have no idea how a TVT would cause chronic pain in the groin. To me, that doesn't make any sense. So as to why they would have something like that in there, I don't know.

Q Can you let me know what other items you don't believe are possible for the TVT device to cause?

A I'll just go to the first bullet point. Those things can occur. Second bullet point, yes. Third is a warning, absolutely. Fourth, those can occur. Risk of infection, absolutely. Overcorrection, correct. Acute or chronic pain -- acute pain, yes. Chronic pain, again, that one I'm not so clear as to how the TVT would

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cause that.

Voiding dysfunction we discussed previously. The pain with intercourse, as I said, I haven't seen that, so I'm not sure why that's in there. We talked about the next bullet point. Recurrence of incontinence we talked about. Bleeding we talked about that that can occur. Revision surgeries are possible, we talked about that, that can occur. And with the last bullet point I would also agree to that.

Q And for the other adverse reactions, which of those do you believe are not possible with the TVT device?

A Well, again, I don't think the device itself causes death. I think they're talking about placing the device. For example, getting into the external iliac artery and having the patient bleed out would cause death, I don't think the device itself causes death.

Q Are you aware of any reports of patient death to Ethicon that don't involve a valve perforation or a bladder perforation?

A I'm sorry?

Q Are you aware of any reports of patient death involving the TVT device that have been made to Ethicon from something other than a bladder or bowel perforation?

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A I'm not aware of -- I don't know what reports have been made to them regarding patient deaths.

Q I'm going to show you what's been marked as Exhibit 5, which is an earlier version of the TVT IFU.

(Whereupon Plaintiffs' Exhibit 5 was marked for identification.)

BY MS. COPE:

Q And if you'll turn to Page 5 there is also an adverse reaction section, do you see that?

A Yes.

Q And you would agree with me that the adverse reactions listed in the 2015 IFU were much more extensive than the adverse reactions listed in the 2010 IFU, correct?

A Correct.

Q And do you have any reason to believe Ethicon would put in these additional warnings if they did not believe that it was important and that they were potential adverse reactions to their products?

MR. KOOPMANN: Object to the form, foundation.

THE WITNESS: Again, I don't know why they put them in.

BY MS. COPE:

Q Do you believe that Ethicon is responsible for telling physicians how to properly tension the TVT

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device?
A No, that should be our experience and that's part of being a surgeon.
Q Well, part of your experience is getting trained by Ethicon about how to place the device, correct?
A Correct.
Q And they taught you how to tension the TVT, correct?
A Correct.
Q So have you changed how you tension the TVT from how Ethicon instructed you?
A The method that I use is similar. I actually tension it a little more loosely than I was originally taught to.
Q And why is that?
A Because I got less retention and still got good results by tensioning it two millimeters less than I had initially.
Q Did you ever communicate to Ethicon that you thought their method they were teaching was unnecessary or involved too much tension on the device?
A I let them know what I was doing and the success I was having with it.
Q And who did you --

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A And again --
Q Go ahead.
A Again, that's for me, my practice and my patients.
Q And who did you let know at Ethicon?
A I talked -- I believe I talked with the representative, local representative about it.
Q And the first time that you deviated from Ethicon's teaching for tensioning the device, did you tell your patient that you were going to perform the procedure differently?
A I don't recall.
Q Do you think it would be important to inform your patient that you were straying from the manufacturer's instructions in performing the procedure on her?
A I don't believe that I strayed in the manufacturer's instructions. If you look at the IFU it doesn't give an exact number for how to tension it.
Q Where in the IFU does it talk about tensioning?
MR. KOOPMANN: Which IFU?
MS. COPE: Either.
THE WITNESS: That would be on Page 4, Paragraph 18.
MR. KOOPMANN: Exhibit 5?

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MS. COPE: It's the 2010.
THE WITNESS: Yes. Now, I assume that this would be -- would this be the same as the 2003 one, do you know?
BY MS. COPE:
Q Approximately. I believe there were some minor changes, but not very substantial.
A Okay, so making the assumption that this paragraph is the same as 2003, it talks about tension, and they don't give an exact number.
Q It says, "Avoid putting tension on the implant."
A Yeah.
Q And that "A blunt instrument should be placed between the urethra and the implant during the removal of the implant sheaths," correct?
A Correct.
Q So it's your testimony that Ethicon doesn't provide instruction on tensioning of the device to surgeons?
MR. KOOPMANN: Object to the form, misstates testimony.
THE WITNESS: That's not my testimony. You're misstating what I said. They don't give an exact number for how many millimeters of spacing to use.

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BY MS. COPE:
Q But they do teach surgeons how to tension the device, correct?
A Correct.
Q And as the manufacturer of the device don't you think it's their job to teach surgeons how, in their experience, it should be used in patients?
A It's up to the surgeon to make those decisions.
Q How is the surgeon going to make those decisions if they've never done the procedure before?
A As I was going to say, they give us a starting point. It's up to us as surgeons to evaluate our patients, our experience, and how we do things.
Q So let's talk about the starting point that Ethicon gives physicians for tensioning. If you could go back to the 2015 IFU on Page 4, Number 17, it says, "The ends of the implant are then pulled upward to bring the implant loosely, i.e., without tension under the mid-urethra."
A Uh-huh.
Q And then if you go on to Page 5, that top bullet point says, "Ensure the tape is placed with minimal tension under the mid-urethra."
A Correct.
Q And then on the first page the actual name of

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the product is Tension-Free Support, correct?
A Tension-Free Vaginal Tape.
Q So which is it, should the mesh be placed with minimal tension, with no tension, without tension? Is it clear to you from this document?
A Let me see. Okay, so 18 says to avoid putting tension on the implant. It's hard to quantify minimal, so I don't know why they use that particular verbiage.
Q And do you tension -- strike that.
You testified earlier that you don't know whether you're using a mechanical cut TVT versus a laser cut TVT in your patients, so is it safe to assume that you do not implant or tension the laser cut or the mechanical cut TVT differently?
A Correct.
Q Anyone from Ethicon ever told you that the tensioning needed to be different depending on whether it was laser cut or mechanically cut?
A No.
Q I'll show you what's been marked as Exhibit 6.
(Whereupon Plaintiffs' Exhibit 6 was marked for identification.)
BY MS. COPE:
Q While you're reviewing that I'll read the Bates number into the record, since it's cut off on the copy.

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It is ETH.MESH.03916905. Do you know who Aaron Kirkemo is?
A No.
Q He's the, or was at the time of this e-mail in 2009, the associate medical director of Ethicon. And I'd like to draw your attention to the second to the last page.
And at the end of the first paragraph of Number 4 it reads: "That being said, I used laser cut mesh in my clinical practice, and after some painful initial experience realized that it performed differently from mechanically cut mesh. I had to lay my laser cut mesh slings in much tighter than the mechanically cut ones."
A Okay.
Q So you disagree with the medical director of Ethicon about how to tension mechanically cut versus laser cut slings?
MR. KOOPMANN: Objection.
THE WITNESS: He doesn't address the type of tension that I use at all. And I don't know, is this TVT or is this TVTO? This looks like it's TVTO.
BY MS. COPE:
Q Well, it's addressing the differences --
A Yeah, this is TVTO. This is not what I do.

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Q So you don't care that the medical director of Ethicon thinks that you need to tension laser cut mesh verses mechanically cut mesh differently?
A For a TVTO, no.
Q If the device -- or sorry. If the TVT mesh is not tensioned correctly, do you believe that's the fault of the physician?
A Okay.
Q If the TVT device is not tensioned correctly, do you believe that is the fault of the implanting physician?
A What do you mean by "correctly" and how are we determining whether it's correct or not?
Q What is your definition of correct tensioning?
A Well, correct tensioning the patient is able to void, but doesn't lose urine when they cough or sneeze.
Q So if that's not the case, do you believe that it is due to over-tensioning of the TVT device?
A For urinary retention it's either -- again, assuming just the mechanical portion of it and there are no other things adding into it, for retention, if it's immediate retention I would be concerned about the effect of the -- and, again, we're talking about my -- I'm sorry, are we talking about my practice or in general?

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Q You just defined for me what you meant by the device being tensioned correctly, so I'm asking you if it's not tensioned correctly, do you believe that's the fault of the implanting physician?
A It can be the fault of the implanting physician for making it too tight. It can also be reaction to medications that are given at or around the time of surgery, including local anesthetic.
It can also be the way that particular patient heals up. Those are all things that you would need to look at if you're looking at somebody with retention.
Q What specific medications are you talking about that could affect the tensioning of the sling?
A Oh, narcotics -- they don't affect the tension of the sling, they affect retention. They don't affect the tension of the sling.
Q I'm just talking about instances where the tension of the device is not correct.
A Okay.
Q Is that the fault of the physician?
A Well, again, we were talking about how we were determining whether it was tensioned improperly or not, so we were talking about retention as one of the ways that you know whether or not it's properly tensioned. So I'm not sure -- do you want to re-ask the question?

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Q Well, you gave a definition of what it meant for the device to be properly tensioned.
A Right.
Q And so in patients where it's not properly tensioned, according to your definition, is that the fault of the implanting physician?
A And, again, that can -- if you're talking about immediate tensioning that's different than the long-term tensioning, because the patients scar up, the scarring is going to retract a bit.
Q So for immediate tensioning.
A Immediate tensioning? And we're talking about retention or we're talking about --
Q We're just talking about the sling not being correctly tensioned under your definition of that term, is that the fault of the implanting physician?
A I'm really sorry, I'm not understanding what you're asking me, because -- well, I don't know how I know that it's improperly tensioned.
Q Do you treat women who have mesh sling complications who have been implanted by other physicians?
A Yes.
Q And approximately what percentage of your practice is spent treating mesh sling complications?

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A Very small. Less than one percent.
Q And what complications do you see in that patient population?
A I have seen retention, I have seen stress incontinence. Those are the two. Again, we're talking strictly slings, correct?
Q Correct. And in any of those instances where you have treated women for retention or recurrent SUI following sling placement, do you believe that any of those were attributable to incorrect tensioning of the device at implant?
A Okay, again, it wasn't recurrent stress incontinence, it was immediate and persistent stress incontinence. And in the cases that I recall, there was a problem with how they were either tensioned or placed.
Q And how do you know in those cases that there was a problem with how it was tensioned or placed?
A By reviewing the records for the retention. Again, I haven't seen one of those cases for a while. I believe it was a records review. And the other one was the --
Q I'm just talking about patients you have treated, not cases where you have served as an expert.
A No, I haven't served as an expert.
Q Why would you just do a records review for

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someone as opposed to seeing them?
A No, you asked me how I would know about the tensioning.
Q Uh-huh.
A That was through records review.
Q Okay, what in the record indicated to you that there was a tensioning issue?
A In that particular case they placed the mesh directly against the urethra.
Q And did you talk to the implanting physician to understand what he meant by what was dictated in his operative note?
A No.
Q And that was for the case with the urinary retention, correct?
A Correct.
Q And for the case in which the device failed and the SUI was persistent?
A The device had been placed superior to the urethral vesicle junction.
Q And how did you treat that?
A Just removed the device and removed -- I didn't remove the entire device, I removed, like, four or five centimeters, just what was under the bladder, and then we put a sling in to take care of her stress

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incontinence.
Q And in all of the patients that you have treated, including the ones in which you have implanted a mesh device, have you ever had to put in a second mesh sling?
A I've had one patient where we had to put in another sling.
Q And did you completely remove the first device that you placed?
A No.
Q You just put the second one in over it?
A Uh-huh.
Q And you have never been told by Ethicon that it was not okay to do that, correct?
A Correct.
Q Would you agree that it's easy to overtighten the TVT device?
A I haven't found it to be so.
Q I'll show you what's been marked as Exhibit 7.
(Whereupon Plaintiffs' Exhibit 7 was marked for identification.)
BY MS. COPE:
Q Let me know when you have had a minute to review.
A Okay.

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MR. KOOPMANN: Do you have the Bates number for this one?
MS. COPE: I do, it's ETH.MESH.03910418.
MR. KOOPMANN: Thanks.
MS. COPE: Thank you for reminding me.
BY MS. COPE:
Q Okay, so on the second page, just about in the middle, it says, "Number 1."
A Okay.
Q "With TVT over tightening it is easy to achieve since there is no limitation when one pulls on the tapes. If you pull sufficiently you will compress the urethra." So would you agree that it's easy to overtighten the TVT device?
A If you pull too hard.
Q And define "pull too hard."
A Well, if you're pulling it hard enough that the TVT is deformed because of the pressure you put on it, if it's compressing the urethra, that's overtightened.
Q On Page 17 of your report -- you can put those out of the way.
A All right.
Q It's the first full sentence of Page 17, "When the mesh is properly implanted as set forth in the IFU and as explained in Ethicon's professional education

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seminars and publications, roping or curling of the mesh are not an issue."
A Right.
Q Can you tell me what you mean when you say they are not an issue?
A If you don't put too much tension on it, it won't rope or curl.
Q And what would be the clinical significance of a TVT device roping or curling in a patient?
A Well, biomechanically you would have less support area. So instead of having something a centimeter wide you might make it into half a centimeter wide, so you're not giving the urethral support you'd like to get.
You're also doubling over the mesh so that it's harder for fiberglass to grow through and properly put the mesh in place. You also run the risk of actually kinking the urethra when you do that, because you have a harder ledge that's pushing -- potentially that is pushing up on the urethra.
Q I'm going to show you what has been marked as Exhibit 8. The Bates number is ETH.MESH.01822361.
(Whereupon Plaintiffs' Exhibit 8 was marked for identification.)
///

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BY MS. COPE:
Q Have you seen this before?
A No.
Q In the second full paragraph, "From an engineering perspective, the laser cut mesh of TVT SECUR has less potential to cause retention than TVT or TVT Obturator because the tape will remain flat under the urethra.
"TVT and TVT Obturator would curl and rope, which reduces the surface area of the mesh under the urethra and, therefore, increases the pressure in a localized point."
So, obviously, Ethicon has received reports or is aware that the device can rope and curl, correct?
MR. KOOPMANN: Object to the form, foundation.
THE WITNESS: Again, I don't know what he's talking about for this. I don't know if he's talking about in vivo or in vitro.
BY MS. COPE:
Q What if he's talking about in vivo?
A Well, that would require me to speculate, wouldn't it?
Q I'm not asking you to speculate.
A So what exactly do you want me to speculate as to?

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Q Well, you said you didn't know what it meant because you weren't sure if he means in vivo or in vitro.
A Correct.
Q So if he means in vivo, what does this mean to you?
A That they've had cases where it roped or curled. I assume that would be what that had meant, but, again, that is speculation.
Q Is that a defect in the mesh for it to rope or curl inside a woman's body?
MR. KOOPMANN: Object to the form.
THE WITNESS: Again, we have gone over that. If you pull too hard on it, it will rope or curl. If you place it tension-free, it won't do that. And when you get fibroblastic infiltration it will remain flat.
BY MS. COPE:
Q But, again, we're not really clear what placing it tension-free means because the IFU states tension-free or minimal tension, you said that isn't very clear.
MR. KOOPMANN: Object to the form.
THE WITNESS: Again, if you put too much tension on it, it will rope or curl.
BY MS. COPE:
Q You can put that aside. Have you reviewed any

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Ethicon documents stating that fraying of the TVT device is a defect?
A No.
Q I'll show you what's been marked as Exhibit 9.
(Whereupon Plaintiffs' Exhibit 9 was marked for identification.)
BY MS. COPE:
Q The Bates number is ETH.MESH-01813975. If you'll look at the second page there's a little caret that states: "The mesh frayed is the reverse defect of the mesh features." Have you seen this document before?
A No.
Q Have you seen complaints from physicians to Ethicon stating that the TVT device frays?
A I have not seen that.
Q That the TVT device sheds particles?
A No.
Q If you'll look at the next caret or paragraph it says, "However, the root cause of this phenomenon are known: The way to cut the mesh, blade cutting. If we change the way to cut the mesh, ultrasonic cutting or laser cutting, it seems we can limit the mesh frayed defect significantly, but this needs to be proved after a very detailed study, which is not still done."
Does this change your opinion that the

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properties between mechanical cut mesh and laser cut mesh are different?
A Again, without knowing what -- I really don't know what this e-mail is about. So I would be hesitant to -- I mean, I don't know the antecedent incident that brought up this e-mail in the first place.
Q Well, unfortunately, this is all Ethicon has provided to us.
MR. KOOPMANN: Object to the form.
THE WITNESS: Then I can't even begin to speculate about this. I don't know if they found frayed mesh in a package, if this occurred in a patient.
BY MS. COPE:
Q Did you review Ethicon e-mails as part of your preparing and writing your report?
A No.
Q Have you seen any documents from Ethicon stating that the TVT device degrades or can crack?
A I'm sorry?
Q Have you seen any documents from Ethicon stating that the TVT device can degrade or crack?
A I have seen -- I, in fact, provided you with some articles, but I'm not sure if they're from Ethicon or not.
Q The articles you're talking about that are

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published literature, correct?
A Correct.
Q I'm going to show you what's been marked as Exhibit 10.
(Whereupon Plaintiffs' Exhibit 10 was marked for identification.)
BY MS. COPE:
Q These are pages from a PowerPoint and you'll see at the bottom it was prepared by PA Consulting Group for Johnson & Johnson.
A Uh-huh.
Q And the Bates number for the entire presentation is ETH.MESH.07192929. And if you look at the third page the slide states: Polypropylene can suffer from degradation following implant. Polypropylene has a long history of use, but it is subject to degradation of process which initiates after a few days post implantation in animal studies."
And the last hash mark says, "High resolution images of excised meshes clearly show physical degradation of polypropylene filaments." Were you aware, prior to seeing this document, that the TVT device degrades?
MR. KOOPMANN: Object to the form, foundation.
THE WITNESS: I was aware that polypropylene

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can have some minimal degradation in the body. Basically, everything we implant in the body will degrade over time.
BY MS. COPE:
Q But specifically were you aware that the TVT device degrades in the body and that process starts shortly after implant?
MR. KOOPMANN: Object to the form, asked and answered, compound.
THE WITNESS: Well, again, they're talking about polypropylene degrading and I assume you're making the jump to the TVT device. Based on that assumption, again, we know that anything we implant in the body will degrade over time.
BY MS. COPE:
Q So you know that the TVT device degrades in the body over time?
MR. KOOPMANN: Objection, asked and answered.
THE WITNESS: Yes, I'm aware of that.
BY MS. COPE:
Q And you stated in your report that you don't believe there are -- let me find the exact one. It's on Page 17 as well. And it's that first paragraph right where we stopped reading last time.
You state: "As far as degradation is

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concerned, again, I have not seen clinically significant degradation of the TVT mesh in my practice, nor have I seen clinically significant degradation described in the published literature, even in those patients on whom I re-operated following a prior mid-urethral sling procedure." What do you mean by "clinically significant degradation"?

A I think the longest implanted mesh that I have taken out had been in for seven years and it was still very strong.

Q How do you know it was very strong?

A Because in taking it out you have to grasp it, you put tension on it to be able to dissect off the surrounding tissues. And if it were fragile, if you put any tension on it, it would crumble and it does not.

Q So clinically --

A It's much stronger than the surrounding tissues are.

Q So clinically significant degradation to you means that the device actually crumbles?

A Well, clinically significant would mean it would have to be falling apart and it doesn't.

Q So you're not aware of any reports to Ethicon of the TVT device crumbling in a patient?

A Not that I'm aware of.

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Q And the patient -- how many patients have you removed a TVT device from?

A Oh, I don't have it sorted out by which devices were implanted, so I can't tell you specifically which were TVT and which were other devices. As far as doing suburethral sling removals, whether they're TVT or TOT devices, probably done about five, I would think.

Q And so in those five patients do you send the excised mesh to pathology?

A Yes.

Q Do you ask the pathology department to do anything other than grossly examine the excised mesh?

A Whatever their protocol is what they do.

Q You don't ask them to examine it under a microscope?

A If that's their protocol they do, and as far as I know, they do.

Q I'm asking you if you have ever asked the pathology department to look at excised mesh that you have taken from a patient under a microscope?

A Again, recalling the reports, they do do a microscopic examination.

Q But you have never asked for it specifically?

A It's part of submitting tissues to pathology.

Q Well, I have seen a lot of pathology reports

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and those cover just gross examination, so I'm asking you if you have ever specifically asked for examination of excised mesh under a microscope?

A No, I haven't, but my pathology department does do that.

Q In the next sentence of your report you state: "If the TVT device degraded, as plaintiff witnesses claim, one would not see the excellent long-term efficacy and safety shown in the published medical literature." Can you tell me how you reached that conclusion?

A Just common sense. If it were really falling apart why would it last so long? And the analogy is we used to use absorbable sutures to do Kelly plication procedures for stress incontinence. Those fail, the sutures get re-absorbed.

Q And have you ever personally looked at mesh either excised or pristine under a microscope?

A No.

Q And you're not a pathologist, correct?

A Correct.

Q And did you ask to see the same documents that were cited in the plaintiffs' expert witness reports?

MR. KOOPMANN: Object to the form.

THE WITNESS: No, I did not.

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BY MS. COPE:

Q Do you know if those were provided to you?

A No, I don't.

Q And going back to Exhibit 10, the third page, the second to the last hash mark reads: "One clinician interview proposed that variability in the raw materials and/or processing thereof could be affecting the clinical performance and outcomes here articulated in his intention to investigate this hypothesis." So this clinician clearly thinks the degradation affects clinical outcomes, correct?

MR. KOOPMANN: Object to form, foundation.

THE WITNESS: Well, this particular paragraph doesn't say anything about degradation, it talks about affecting clinical performance and outcomes.

BY MS. COPE:

Q Well, the whole slide is about polypropylene can suffer from degradation and there's a bullet point that states polypropylene has a long history of use, but is subject to degradation and these are all sub-points underneath that.

A Okay, so. . .

Q So we have at least one clinician who's communicated to this consulting group that's now communicated to Ethicon that he believes it affects

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clinical performance and outcomes, correct?
MR. KOOPMANN: Objection.
THE WITNESS: I don't think that's what it says at all.
BY MS. COPE:
Q What do you think it says?
A They interviewed a clinician. I have no idea why that clinician was chosen. I don't know if they chose the clinician or the clinician contacted Ethicon. And I don't know which clinical performance and outcomes that particular clinician might be concerned about.
Q Did you look at any internal Ethicon documents?
A No.
Q On Page 16 of your report in the final paragraph you state: "In more than 250 uses of the TVT devices in my career, I have not seen any clinically significant particle loss in my patients." What do you mean by "clinically significant particle loss"?
A I haven't -- well, first of all, I haven't seen any particles. Second of all, I haven't had any patients with any adverse events that I could relate to a particle.
Q Well, according to you, the only adverse events you had are urinary retention and an exposure, correct?
A Correct.

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Q Are you aware that particle loss was the reason that Ethicon wanted to use laser cut mesh rather than mechanically cut mesh for their TVT device?
MR. KOOPMANN: Object to the form, foundation.
THE WITNESS: No.
BY MS. COPE:
Q Would that change your opinion about whether particle loss is clinically significant or not?
MR. KOOPMANN: Same objection.
THE WITNESS: No.
BY MS. COPE:
Q Have you seen any medical literature showing increase in complications due to particle loss?
A No.
Q Are you aware of any studies that Ethicon did to see if there were increased complications due to particle loss?
A No.
Q And it's your --
A Can I ask a question? How big a particle are we talking about?
Q Well, you wrote it in your report, so you tell me.
A Well, I mean, particles can be like atom-sized. Again, it's certainly sub my ability to see them.

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Q So there may be particle loss that you can't see is what you're saying?
A Well, that's part of degradation, which, as I said before, happens to anything we put in the human body.
Q So what did you mean when you said that there's been no significant particle loss or you haven't seen particle loss?
A I haven't seen any.
Q If you saw complaints from -- off the record.
(Brief interruption.)
BY MS. COPE:
Q If you saw complaints from physicians about particle loss, would that change your opinion about the TVT and particle loss?
MR. KOOPMANN: Object to the form.
THE WITNESS: I would certainly take those into consideration. I would want to see the reports and see what had actually happened.
BY MS. COPE:
Q Do you think doctors would make complaints to Ethicon about particle loss if they didn't think it was clinically significant?
A Again, without knowing how they're determining particle loss, I really can't say.

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Q Well, how did you determine particle loss?
MR. KOOPMANN: Object to the form.
THE WITNESS: Again, I said that I hadn't seen any.
BY MS. COPE:
Q Well, so what do you mean when you say you haven't seen any?
A Well, I haven't seen -- which is why I asked you what your definition of "particle" was. I haven't seen any bits of the mesh either in the packaging or in putting it in the patients or in examining the patients afterward.
Q So I'm asking you if physicians told Ethicon if they did see particles of mesh going into the patient or in the box once they removed the product, would that change your opinion that it doesn't happen?
MR. KOOPMANN: Object to the form, compound.
THE WITNESS: Run that back again. Would that change my opinion that it doesn't happen?
BY MS. COPE:
Q We'll try to this way: Just because you haven't experienced it in your practice doesn't mean that it doesn't happen, correct?
A That would be correct.
Q I'll show you what's been marked as Exhibit 11.

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(Whereupon Plaintiffs' Exhibit 11 was marked for identification.)
BY MS. COPE:
Q Have you had a chance to review this?
A Yes.
Q And so on the first page, the paragraph that begins "Particle Loss," it states: "Particle loss is the reason why TVT wants to use laser cut mesh to eliminate particle loss, which is critical to quality." So, clearly, Ethicon thought that there was an issue with particle loss of the TVT, correct?
MR. KOOPMANN: Object to the form, misstates.
THE WITNESS: Again, I have no idea what the antecedent problem is.
BY MS. COPE:
Q Well, the antecedent problem is particle loss.
A Okay, but I don't know if it's finding particles in the kit, I don't know if it's particles found in the patient.
Q Does it matter?
A Well, yeah.
Q Well, if there's particles in the container, in the kit, why would you think that there wouldn't be particles that could be lost in the patient's body?
A Well, that's the if. I mean, if you're seeing

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them in the container, you know, in the cutting process those should be gone. So that, to me, seems like it's a packaging problem or something else going on.
Q Do you know how Ethicon packages the TVT?
A I don't know. I have not been to their production lines.
Q But, clearly, Ethicon thought it significant enough to eliminate particle loss with the TVT or attempt to, correct?
MR. KOOPMANN: Object to the form.
THE WITNESS: I know that this person thinks it's important. Again, I don't know -- I really do not know the antecedent problem that they're talking about.
BY MS. COPE:
Q I'm telling you the antecedent problem is particle loss, and they sought reason to eliminate that problem, correct?
MR. KOOPMANN: Object to the form, foundation.
THE WITNESS: Again, I don't know.
BY MS. COPE:
Q It says, "Particle loss is the reason why TVT wants to use laser cut mesh, to eliminate particle loss."
MR. KOOPMANN: Wait for a question.
///

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BY MS. COPE:
Q Are you refuting that statement?
A Again, I don't know who this is. I don't know what it's in reference to, so I can't reasonably make a comment on it.
Q So I'm assuming from your testimony here today that you can't comment on any e-mails from any Ethicon employee that's been produced in this litigation, correct?
MR. KOOPMANN: Object to the form.
THE WITNESS: Not anything that you have produced to me so far.
BY MS. COPE:
Q You testified that you haven't reviewed any up until today.
A Right, so for what you've produced to me so far, I can't comment on these because I don't know the context in which these e-mails were sent.
Q And what would you need to know the context of what the -- of the e-mails sent?
A Well, what they are considering product loss, what their problem was when it happened, you know, what they considered particle loss to be. And, again, I don't have those definitions, I don't know the significance of it.

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Q And you don't know, when you use the term "particle loss" in your report, if you were using the same definition that plaintiffs' experts were using or that Ethicon was using, correct?
A Correct.
Q So how can you refute what plaintiffs' experts are saying if you don't know what they mean by particle loss?
MR. KOOPMANN: Object to the form.
THE WITNESS: I would have to go back and look at their definition. Again, I have not seen any visible particles.
BY MS. COPE:
Q And you haven't seen any of the documents that are cited in plaintiffs' expert reports, correct?
MR. KOOPMANN: Objection, and please let her finish her response, too. I think she got cut off.
MS. COPE: And if you could keep your objections to form, as the judge has ordered in this case, I'd appreciate it.
MR. KOOPMANN: I just want the witness to be able to complete her answers and not be interrupted.
THE WITNESS: Okay, can you repeat the question, please?
MS. COPE: Can you please read back the

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question?
(Record read as:
"Q And you haven't seen any of the documents that are cited in plaintiffs' expert reports, correct?")
THE WITNESS: I have provided you with all the documents that I have seen, so I don't know -- without cross-referencing those, I don't know whether or not I have seen their articles or not.
BY MS. COPE:
Q But you haven't seen any documents that are internal Ethicon e-mails like this, which have a Bates number at the bottom, up until today, correct?
A Correct.
Q I'll hand you what's been marked as Exhibit 12.
(Whereupon Plaintiffs' Exhibit 12 was marked for identification.)
BY MS. COPE:
Q And this is a letter or a handout to the Ethicon Women's Health and Urology Sales Force, correct?
A Yes.
Q And the paragraph that begins, "Currently, Gynecare Prolift," and the second sentence reads: "In an effort to gain efficiencies in manufacturing processes, we decided to explore the impact of cutting

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our present Gynecare TVT products on the laser cutter. We found by doing so we reduced particle loss, as well as the potential for mesh fraying."
So, again, Ethicon was trying to address the problem of particle loss and the Gynecare TVT mesh fraying, correct?
A It appears that they were.
Q And in one of the last statements here it says, "The laser cut mesh will be available for you to sell as needed, particularly to customers that have voiced concerns regarding particle loss and fraying."
So even though you have never seen it, Ethicon is stating here that they have received complaints of particle loss and fraying of the TVT device, correct?
MR. KOOPMANN: Object to the form.
THE WITNESS: It appears that they have had customers voice that concern. And, again, I don't know if they're concerned about it or if they actually had cases where it was important.
BY MS. COPE:
Q Do you think Ethicon would try and fix the problem if it wasn't important?
MR. KOOPMANN: Object to the form.
THE WITNESS: You know, I can't even begin to speculate on that.

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BY MS. COPE:
Q Have you made complaints to Ethicon about their products for reasons that you didn't believe were important to your patients?
A I haven't made complaints to Ethicon.
Q During any of your training or interaction with Ethicon, did they tell you how to remove the TVT device in case of complications?
A I don't believe that they did.
Q Did you ever communicate to the sales representatives that would come and watch your procedures how to remove the mesh or treat complications from the TVT device?
A I don't recall that I did.
Q I'll hand you what's been marked as Exhibit 13. This is the chart that was attached to your report, correct?
A Uh-huh.
(Whereupon Plaintiffs' Exhibit 13 was marked for identification.)
BY MS. COPE:
Q Can you tell me who prepared this report?
A I did.
MR. KOOPMANN: Object to the form. You mean the report or this table?

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MS. COPE: The table.
THE WITNESS: Oh, I prepared it.
BY MS. COPE:
Q And can you tell me for the skill level required what that key means of the pluses?
A Oh, it's from difficult -- like two pluses would be fairly simple, three pluses moderately difficult, and four pluses more difficult.
Q And is that a system that you came up with to rate difficulties?
A Yes.
Q And for the data that you gathered for the TVT column, do you know how much of that data related to mechanically cut TVTs versus laser cut TVTs?
A I don't.
Q For the Trans-Obturator column, does this include all Trans-Obturator products or specifically the TVT Obturator?
A All Trans-Obturator products. Similarly for the TVT. That's all suburethral slings -- retropubic suburethral slings.
Q But all suburethral polypropylene slings are not identical or interchangeable, correct?
A Correct.
Q So how is it fair to lump all the data for

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mid-urethral retropubic polypropylene slings into this one column?
A It was taking them as a whole. And, again, it is compilation based on a number of studies.
Q But if this report and your opinions are about the TVT, why did you feel the need to do a compilation of all retropubic MUS's?
A Well, because I considered this instructional to try to compare -- since there are no head-to-head, randomized, controlled trials comparing all of these different methods, and I thought that this would be a simpler way to look at each individual procedure and looking at various aspects of it, how hard it is to do, what the impact is on the patient, risk of retention, et cetera.
So it was just -- it was a compilation of things similar to what the Cochrane report does when they compile various studies.
Q But the Cochrane review has already done this analysis, correct?
A Yeah, and I use their data for a bunch of it.
Q So why did you feel the need to redo it if the Cochrane has already completed the same analysis?
A Well, they didn't have all the things that I have in here and -- may I finish?

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Q I was just going to ask you to specify which things that were in here that were not included.
A Can I finish what I was saying first?
Q Sure.
A Okay. And I just found it a very simple way to refer to the different types of things rather than write it out as a paragraph or two or five.
As far as which ones are Cochrane and which ones are not, I believe most of this is included in the Cochrane, then I specifically put in areas which I got from other studies, because they weren't necessarily included in the Cochrane report.
Q And how did you choose the studies that you did?
A On Google I looked for studies that address those particular issues that I was trying to compare from one type to another.
Now, looking at this you have to be aware that these are not head-to-head studies and this is not meant to be a comparison saying that, you know, Burch is better than laparoscopic, Burch is better than whatever. It's just a way of looking at them to make the data more accessible.
Q And this isn't something that's been peer reviewed or published, correct?

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A Oh, no, no.
Q And in terms of the cost row, can you tell me what your system of pluses means there?
A Again, what cost the least versus what cost the most. And it's based on not only the cost of the operation and the hospital stay, but to the cost of the patient because of time off work. And, again, that's my own system.
Q And does that include the cost of any re-operations or times spent treating complications?
A I did not include that in it. But that would be a good column to put in, too.
Q And same for time off work, that doesn't include time off work that's needed for any re-operation or treatment of complications, correct?
A Correct.
Q Or any disability from long-term complications, such as chronic pain?
A Correct.
Q And on Page 14 of your report -- I think I'm done with everything else except your report.
A Okay, I'll put those to the side. Do you need these back?
Q You can put those to the side and we'll give them to the court reporter. On Page 14, about the fifth

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line down, you're quoting from SUFU and AUGS, I believe, that there's a broad evidence base including high quality scientific papers. Can you tell me what high quality scientific papers mean to you?
A Things that are peer reviewed, randomized -- in this case because it's surgery, randomized controlled trials, longitudinal studies where they're looking at patients over time.
Q And the AUGS-SUFU physician's statement isn't peer reviewed, correct?
A It's based on peer-reviewed materials.
Q But the statement itself is not peer reviewed before it's published, correct?
A Well, it's reviewed by experts, so I guess to the extent that these are experts, these are the people who would peer review papers --
Q Is there a formal peer review process for statements that come from AUGS or SUFU?
A Again, I'm not privy to that, don't know the process that they use.
Q And ACOG practice bulletins are not peer reviewed, correct?
A Again, it's not like peer-reviewing a scientific paper, but it's a committee opinion. These are the experts, these are the peers who review the

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papers, and it's their opinion based on the literature.
Q Is there a peer review process for ACOG practice bulletins that you're aware of?
A I would have to check with ACOG.
Q So you're not aware of any as you sit here today, correct?
A I don't know their process for determining what they publish. These are the people who do the peer reviews.
Q And there are also some people who serve as consultants for medical device companies, correct?
A If they do, those are disclosed.
Q Well, they're supposed to be disclosed, correct?
A That's the ACOG policy.
Q And on Page 2 of your report, you talk about the nonsurgical methods for treating stress urinary incontinence. How often do you use those in your practice?
A All the time.
Q With what percentage of patients that have stress urinary incontinence being diagnosed?
A Okay, every -- well, I encourage everybody to use Kegel exercises if they're overweight. I encourage them to lose weight. If they're estrogen-deficient we

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talk about estrogen replacement therapy, either locally or systemically, again, depending upon the patient's wishes and desires for that.
So that's prior to even doing any kind of cystometrograms. I usually review -- sorry, reserve those for patients who are at the point where they are considering going on to surgery to see if surgery is going to be appropriate for them or not.
We have pelvic floor training that we do with neurostimulators. I'll put in pessaries for patients who would like to use them.
Q Those who don't wish to have surgery or are not good surgical candidates?
A Correct.
Q Can you tell me what your definition of "not surgical candidate" is?
A Somebody with severe heart disease, multiple medical problems, diabetes, hypertension, renal failure where putting them under anesthesia might be a danger to them. Nursing home patients, patients with Alzheimer's.
Q And do you know why Ethicon has never sent any doctors to you to be trained?
A No.
Q And in your summary of opinions on Page 3, you talk about your personal experience where you say, "I

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personally have found." Are these numbers that you're giving in this sentence, are they yours, those of your practice?
A In the second paragraph, "I personally found"?
Q Correct. Is this based on your clinical experience?
A What line?
Q How quick it is and the effectiveness and your one redo.
A Oh, got it. I'm in the wrong place. This is based on what it takes for me to do them.
Q But you personally, not you and your partner, correct?
A No, though his usually take about the same time as mine do.
Q I meant for all these numbers, the 90 percent efficacy and the numbers of mesh exposures of urinary tensions?
A No, those are mine, not his.
Q And how do you track your 90 percent efficacy rate?
A Because I practice primary care. These are my patients for the most part, so I'll see them back for years afterward and see them on an annual basis.
I also have very good relationships with my

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referral sources, so when I have a patient referred in for a problem and do a surgery on them, they're, first of all, told if they have any problems they can come back anytime.
We also let the referral sources know that should the patient develop any problems or questions that they should call us.
Q And how many patients do you lose to follow-up?
A You mean for my practice, period?
Q Yes.
A Okay. Percentage-wise you mean?
Q Sure.
A Okay. Boy, maybe 10 percent, 15. It's not very much.
Q But you don't obviously know the outcomes of those 10 to 15 percent of your patients?
A Correct. But I assume that they would reflect the patients that I -- for the most part reflect the patients that have continued to see me.
Q And what's the basis for that assumption?
A Just that they would be similar populations.
Q And later on in that paragraph you say that you have very good patient acceptance. Can you tell me what you mean by "patient acceptance"?
A Patients are usually very willing to do the

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procedure. Obviously, if somebody is not willing to do it, we do not do it. They are generally very pleased with the outcomes. There's nothing like coughing and not wetting your pants to make your day.

Q And on Page 4 under "Risk Factors for Stress Urinary Incontinence," one of the things you list is nerve injuries to the lower back.

A Correct.

Q Can you be more specific about what types of nerve injuries?

A Prolapsed discs, any kind of back injury, anything that would cause sciatica, nerve root irritation, something like spondylitis where you get -- or osteoarthritis of the spine where you're going to get impediment of the motor neurons.

Q And you note castration here also.

A Uh-huh.

Q Have you seen that in your female patients?

A Where we take out their ovaries, that's castration, so they go into menopause.

Q And that can induce stress urinary incontinence?

A It can contribute to it, because when you lose estrogen supply you actually decrease the amount of blood supply to the pelvic musculature, the muscles get

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thinner, weaker, so that can be a factor.

And the mucosa also thins out so you have less -- the mucosa goes from 26 layers down to 5 layers. You go from nice, big fat cells to these little, thin flat cells.

And the estrogen also affects the bladder and the urethra. You'll have a urethra that has all these nice folds and thick mucosa in it before women go through menopause, whether it's surgical or natural, and afterward they get de-estrogenized enough that it will look like a lead pipe, there will be no folds at all and no support to it.

Q And on Page 8 of your report in the second line from the top, you state that non-absorbable sutures can erode through surrounding tissues.

A Yes.

Q How many times have you seen a non-absorbable suture erode through surrounding tissues in your patients?

A Oh, maybe half a dozen.

Q And how would you treat that or how did you treat that?

A Well, it would be encountering the sutures on a secondary surgery where patients had had a -- usually they've had retention sutures put in to close an

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abdominal wound. Do you know what retention sutures are?

Q Uh-huh.

A Okay. I didn't want to tell you stuff that you didn't --

Q Good assumption.

A Okay, I don't want to speak above your pay grade.

So those are sutures that have a lot of tension on them to begin with, obviously, even when we put rubber shods on them to help keep the tension off, and sometimes we can see those going through the fascia. So when that happens we take them out. And, of course, if we're doing another surgery we're taking them out anyway.

Q And in those half a dozen times you have seen the non-absorbable suture erode and treated it, have you seen any long-term problems with those patients as a result of the non-absorbable suture?

A No.

Q And I just want to make sure I'm clear, on Page 10, the list you give with percentages at the top, is that taken directly from the table that we have already looked at?

A This is from the Cochrane video.

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Q So you're just listing what was in the Cochrane review?

A Right.

Q And same thing for the chart below it, correct?

A Correct. SGS, I believe that's the site of gynecological surgeons review.

Q And are there any opinions that you are planning on offering at trial that are not included in this report?

A None that I know of at this time. Obviously, the medical field is not static. We're going to be getting new -- I mean, new data comes out all the time, new studies, papers. I may have a patient experience that I haven't had yet that will obviously affect how I testify at trial.

MS. COPE: I'm going to go ahead and reserve the rest of my time for any redirect, so I have no further questions at this time.

MR. KOOPMANN: Okay.

EXAMINATION

BY MR. KOOPMANN:

Q Dr. Bergmann, there was a question earlier about Gynemesh. Is it your understanding that the TVT mesh is different than Gynemesh PS?

A Yeah, because there's several different grades

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of Gynemesh is my understanding, so I know it's. . .
Q In how many patients that you have implanted the TVT in have you seen chronic pain as a complication?
A None.
Q Did you ever -- there were some questions earlier about another manufacturer's mesh causing fraying that caused some strands of the polypropylene to poke through the vaginal mucosa.
My question is: Did you ever see any fraying with the TVT slings that you have used in your career that caused the mesh to poke through the mucosa?
A No.
Q Ms. Cope asked you some questions about whether it's easy to over-tension the TVT device and my question for you is: Is it also easy to not over-tension the TVT device?
A You guys are asking questions that don't exist in the real world.
MS. COPE: That's what we do.
THE WITNESS: I know. You have to treat it gently. You don't treat it like a rubber band.
BY MR. KOOPMANN:
Q There was some discussion earlier about degradation of any implanted materials in the body. If, for instance, somebody has a metal plate put in their

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body does that degrade?
A Yes.
Q And how do you know that implanted materials, all of them, to some extent experience degradation?
A Well, it's second law thermodynamics, everything degrades over time. And I have seen studies -- actually, I looked up information, and I didn't get that to you because I didn't keep it, it was online, but basically everything we implant in the body will degrade over time, including gold, which is a very inert material.
Q Do you practice evidence-based medicine?
A I practice evidence-based medicine as is appropriate for the patient sitting in front of me.
Q And what does evidence-based medicine mean?
A It's medical practice that's based on algorithms that are set up using peer-reviewed studies. Whenever possible we try to use randomized, double-blinded control trials. If you can do double-blinded, randomized control with a crossover, those are the very best ones.
Q So there are different levels of evidence, some are better than others?
A Yes.
Q And what do you consider the highest levels of

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evidence to be?
A As I said, double-blind and randomized crossover trials.
Q Are systematic reviews and meta-analysis also high quality evidence?
A They're lesser quality. Again, whenever you add a meta you're not comparing exactly the same things and they try to get as close as they can without -- you know, given that limitation.
So I look at them, I consider them. I don't consider them as strongly as I would a randomized, controlled trial, double-blinded, of course.
Q Can you think of any randomized, controlled trials that show that the TVT mesh degraded and that was clinically significant in some way?
A No, I don't know of any.
MR. KOOPMANN: Counsel, do you want to -- are you going to go through her file materials and mark them?
MS. COPE: I wasn't and yes.
BY MR. KOOPMANN:
Q As part of your file materials you brought along various articles that are in your file; is that correct?
A Correct.

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Q And some of those articles discuss the complication rates seen with TVT slings or other retropubic slings over time?
A Correct.
Q They discuss things like erosions, for instance?
A Yes.
Q Or mesh exposures?
A Correct.
Q And they describe the rates of those erosions to exposures occurring?
A Yes.
Q They describe things like the number of patients or the percentage of patients who have an erosion or an exposure and have to have a re-operation, correct?
A I believe that's in there, yes.
Q And how would you characterize those rates of re-operation following a mesh erosion or exposure based on all the literature you have reviewed?
A Quite well.
MR. KOOPMANN: Those are all the questions I have right now.
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RE-EXAMINATION
BY MS. COPE:
Q I just have one follow-up question. Who provided you with this stack of articles that Counsel was just looking through?
A Counsel provided me with almost all the articles -- for this (indicating), that was from Counsel.
Q And had you seen any of these prior to them being given to you by Ethicon's attorneys?
A I don't believe I had seen that particular group. There may be a couple in there that I have seen before.
Q Okay. Then I would just like to spend the rest of the time cleaning up the record and marking all exhibits, so I'll take this stack of articles that we just mentioned and mark that as Exhibit 14.
(Whereupon Plaintiffs' Exhibit 14 was marked for identification.)
BY MS. COPE:
Q There is also a group of bills that you have produced and I'll mark it Exhibit 15.
(Whereupon Plaintiffs' Exhibit 15 was marked for identification.)
MS. COPE: And a bound set of documents

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entitled, "TVT Development and Early Data," I'll mark it as 16.
(Whereupon Plaintiffs' Exhibit 16 was marked for identification.)
BY MS. COPE:
Q This Exhibit 16 was prepared for you by Counsel or provided to you by Counsel, correct?
A Right.
Q And there is a binder that is labeled, "General Report and Sources," was this also prepared or given to you by Counsel?
A Yes. It's a copy of my report and then everything is referenced in case you wanted to look at any of the -- well, because a lot of that stuff is on the thumb drives, so that way we didn't have to get it from the thumb drives.
Q I'll mark this binder as Exhibit 17.
(Whereupon Plaintiffs' Exhibit 17 was marked for identification.)
MS. COPE: And there's another binder labeled, "Ethicon Gynecare Pelvic Mesh Litigation, TVT Medical Literature," and I'll mark that as Exhibit 18.
(Whereupon Plaintiffs' Exhibit 18 was marked for identification.)
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BY MS. COPE:
Q And, again, this binder was prepared by or given to you by Counsel, correct?
A Correct.
Q And there is the -- does this go in the other stack, do you know?
MR. KOOPMANN: I think so.
Was that a part of the other stack?
THE WITNESS: Oh, no, this is one of -- that's something that I looked at, because you had asked for any papers that I had looked at. That was one of the ones I had on my computer.
BY MS. COPE:
Q It's "National Institute for Clinical Excellence Final Appraisal Determination Tension-Free Vaginal Tape." And where did you get this document from?
A Internet.
Q I'll mark that as Exhibit 19.
(Whereupon Plaintiffs' Exhibit 19 was marked for identification.)
BY MS. COPE:
Q And you were also given copies of the plaintiffs' expert reports in this bound packet, correct?

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A Correct.
Q I'll mark that as Exhibit 20.
(Whereupon Plaintiffs' Exhibit 20 was marked for identification.)
MR. KOOPMANN: One of those might be Daino related.
MS. COPE: I saw that, yeah.
MR. KOOPMANN: I don't know if you want to separate that out.
BY MS. COPE:
Q If you could look at this for me, Doctor, and tell me what that document is.
A This is from my Internet research and I was trying to figure out how the FDA determines how they do product labeling for devices.
Q So that wasn't something you were aware of prior to being retained as an expert in this litigation?
A No, no.
Q Do you normally look at FDA regulations as part of your job?
A You know, on occasion, depending upon what they've done to us lately, but this -- I'm sorry.
Q Do you look at FDA regulations as they relate to medical devices?
A No, no.

Q Okay, so we'll mark -- it looks like this is an e-mail sending you the device labeling document, correct?
A Right.
Q So I'll mark that as the final exhibit, which is 21.
(Whereupon Plaintiffs' Exhibit 21 was marked for identification.)
MS. COPE: And I believe the rest of these materials relate specifically to individual cases. I have no further questions.
MR. KOOPMANN: The thumb drives?
MS. COPE: Sorry. I'm guessing these are case specific and general?
MR. KOOPMANN: Yes.
MS. COPE: So we will just mark all of these as Exhibit 22.
(Whereupon Plaintiffs' Exhibit 22 was marked for identification.)
MS. COPE: Now we're finished.
(Time noted: 12:13 p.m.)

-oOo-

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed at _____California on_____ 2016.

_____
CYNTHIA BERGMANN, M.D.

STATE OF CALIFORNIA)
) ss.
COUNTY OF FRESNO)

I, Karla M. Rocha, Certified Shorthand Reporter licensed in the State of California, License No. 8982, do hereby certify that the foregoing proceeding was reported by me and was thereafter transcribed under my direction into typewriting; that the foregoing is a full, complete and true record of said proceeding.

I further certify that I am not of counsel or attorney for either or any of the parties in the foregoing proceeding and caption named, or in any way interested in the outcome of the cause named in said caption.

In witness whereof, I have hereunto set my hand and affixed my seal this day.

Date: March 21, 2016

_____
Karla M. Rocha
CSR #8982

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